(2) Suspends or limits the CLIA certificate for less than 1 year based on the criteria in § 493.1804(d) and imposes alternative sanctions as appropriate, in accordance with §§ 493.1804(c) and (d), 493.1806(c), 493.1807(b), 493.1809 and, in the case of civil money penalties, § 493.1834(d), when CMS determines that paragraph (b)(1)(i)(A) or (B) of this section does not apply but that the laboratory obtained test results for the proficiency testing samples from another laboratory on or before the proficiency testing event close date. Among other possibilities, alternative sanctions will always include a civil money penalty and a directed plan of correction that includes required training of staff.

(3) Imposes alternative sanctions in accordance with §§ 493.1804(c) and (d), 493.1806(c), 493.1807(b), 493.1809 and, in the case of civil money penalties, § 493.1834(d), when CMS determines that paragraph (b)(1)(i) or (2) of this section do not apply, and a PT referral has occurred, but no test results are received prior to the event close date by the referring laboratory from the laboratory that received the referral. Among other possibilities, alternative sanctions will always include a civil money penalty and a directed plan of correction that includes required training of staff.

(c) *Adverse action based on exclusion from Medicare.* If the OIG excludes a laboratory from participation in Medicare, CMS suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

(d) *Procedures for suspension or limitation*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, CMS does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in § 493.1844) that upholds suspension or limitation.

(2) *Exceptions.* CMS may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

(i) The laboratory's deficiencies pose immediate jeopardy.

(ii) The laboratory has refused a reasonable request for information or work on materials.

(iii) The laboratory has refused permission for CMS or a CMS agent to inspect the laboratory or its operation.

(e) *Procedures for revocation.* (1) CMS does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) CMS may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) *Notice to the OIG.* CMS notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

[57 FR 7237, Feb. 28, 1992, as amended at 79 FR 25480, May 2, 2014]

§ 493.1842 Cancellation of Medicare approval.

(a) *Basis for cancellation.* (1) CMS always cancels a laboratory's approval to receive Medicare payment for its services if CMS suspends or revokes the laboratory's CLIA certificate.

(2) CMS may cancel the laboratory's approval under any of the following circumstances:

(i) The laboratory is out of compliance with a condition level requirement.

(ii) The laboratory fails to submit a plan of correction satisfactory to CMS.

(iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) *Notice and opportunity to respond.* Before canceling a laboratory's approval to receive Medicare payment for its services, CMS gives the laboratory—

(1) Written notice of the rationale for, effective date, and effect of, cancellation;

(2) Opportunity to submit written evidence or other information against cancellation of the laboratory's approval.

This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the appeals procedures set forth in § 493.1844.

(c) *Effect of cancellation.* Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

§ 493.1844 Appeals procedures.

(a) *General rules.* (1) The provisions of this section apply to all laboratories